

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BOARD OF PATENT APPEALS AND INTERFERENCES

Applicant: Peter M. Bonutti

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For: METHOD OF USING BODY TISSUE

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BRIEF ON APPEAL

This Brief on Appeal is made in Response to the final office action dated April 2, 2010.

Appellant hereby respectfully submits this brief in support of his appeal to the Board of Patent Appeals and Interferences of the final rejection of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 84-85, and 88-111 of the above-referenced application. Reconsideration of the Application, withdrawal of the rejections, and allowance of the claims are respectfully requested.

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PROCEDURAL POSTURE

This is an appeal from the final rejection in the Office action dated April 2, 2010 finally rejecting 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 84-85, and 88-111.

I. REAL PARTY IN INTEREST

The real party in interest in this matter is P TEC, LLC, an Illinois corporation, evidenced by assignment recorded by the USPTO on June 22, 2009 at Reel/Frame 022859/0060.

II. RELATED APPEALS AND INTERFERENCES

No related appeals or interference proceedings are currently pending that would directly affect or be directly affected by or have a bearing on the Board's decision in this appeal.

III. STATUS OF CLAIMS

This is an appeal from the final rejection in the Office action dated April 2, 2010, finally rejecting claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 84-85, and 88-111.

Claims 94 is objected to based on its dependency on claim 96 and under 37 CFR 1.75 as allegedly being a substantial duplicate of claim 92; Claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 are rejected under 35 U.S.C. §112, 1st paragraph; claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 80-111 are rejected under 35 U.S.C. §112, 2nd paragraph; and claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99, and 109 are rejected under 35 U.S.C. §103(a). All pending claims, 36, 38-43, 46-50, 53, 57, 59-61, and 66-111, are under appeal. Claims 1-35, 37, 44, 45, 51, 52, 54-56, 58, and 62-65 were cancelled in previous Response(s). Claims 68-79, 86, and 87 were previously withdrawn by the Examiner.

STATUS OF OBJECTIONS

Claims 94 has been objected to because it depends on claim 96 and for allegedly being a substantial duplicate of claim 92. These objections will be addressed with amendment by Applicant should prosecution be re-opened or could be addressed by an Examiner's Amendment should the application be allowed.

IV. STATUS OF AMENDMENTS

Claims 36, 53, 57, 66, 68-70, 74-76, and 78-79 were amended in a response sent/received December 10, 2009. A *Notice of Appeal* was sent/received on July 2, 2010.

V. SUMMARY OF THE CLAIMED SUBJECT MATTER

Claims 36 and 84 are the independent claims pending in this appeal. The patentability of dependent claims 38-43, 46-50, 53, 57, 59-61, 66-83, and 85-111 is being argued separately.

With reference to at least Fig's. 1-16, 18, 19A, and 19B of the originally filed application and associated text, the present application with respect to independent claim 36 relates to a method of using fetal body tissue and with respect to independent claim 84 relates to a method of using body tissue.

More particularly, the claims follow, with references to the specification and drawings, for at least one embodiment of the invention, for each claim element. Bracketed reference numbers in bold refer to the page number in the originally filed application, followed by a slash, followed by relevant line number(s) on the page. References to the drawings and originally filed claims are within parentheses, and are also in bold.

Claims 1-35. (Cancelled)

Claim 36. (Previously presented) A method of using fetal body tissue [3/20], said method comprising inserting a removal apparatus (**Figs. 1-16**) into a donor percutaneously through a cannula [8/6-14; 22/27-23/5; 23/25-24/14] (**Figs. 18, 19A, and 19B**), guiding the removal apparatus to a desired location within the donor's body [6/5-18; 24/23-27], separating portions of fetal tissue from other portions of the donor [7/3-6; 9/8-10; 20/26-21/12], moving the separated portions of fetal tissue along a passage in the removal apparatus by suction [24/10-18; 25/2-4], maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation [6/21-22; 7/15-17], and implanting the separated portions of fetal tissue in a patient [25/8-10].

Claim 37. (Cancelled)

Claim 38. (Previously Presented) The method of claim 57 wherein a rotating motion [14/22-26] is used to separate [4/2-5] the portions of fetal tissue [3/20].

Claim 39. (Previously Presented) The method of claim 57 wherein a reciprocating motion [11/25-12/5] is used to separate [4/2-5] the portions of fetal tissue [3/20].

Claim 40. (Previously Presented) The method of claim 36 further comprising a step of irrigating [6/24-25] the fetal tissue [3/20].

Claim 41. (Previously Presented) The method of claim 40 wherein irrigating and applying suction alternates [6/24-25].

Claim 42. (Previously Presented) The method of claim 40 wherein irrigating and applying suction occur substantially simultaneously [6/24-25].

Claim 43. (Previously Presented) The method of claim 36 wherein the passage includes a filter [7/3-5].

Claims 44-45. (Cancelled)

Claim 46. (Previously Presented) The method of claim 36 further including, prior to implantation, combining the separated portions of fetal tissue [3/20] with a material selected from the group consisting of tissue grafts, collagen, and bone growth promoting substances [22/5-6].

Claim 47. (Previously Presented) The method of claim 36 further including adding an adhesive element to the separated portions of fetal tissue prior to implantation [8/14-19; 21/20-24; 22/7-9].

Claim 48. (Previously Presented) The method of claim 47 wherein the adhesive element is blood or fibrin [22/7-9].

Claim 49. (Previously Presented) The method of claim 36, further including adding a biodegradable material to the separated portions of fetal tissue prior to implantation [8/17-18, 22/4-6, 23/8-9].

Claim 50. (Previously Presented) The method of claim 36 further including adding a polymer to the separated portions of fetal tissue prior to implantation [23/8-9].

Claims 51-52. (Cancelled)

Claim 53. (Previously presented) The method of claim 36 wherein separating is performed through the cannula [8/7-9, 23/1-3].

Claims 54-56. (Cancelled)

Claim 57. (Previously presented) The method of claim 36 wherein the removal apparatus includes a shaft with a tip [4/1-2, 24/25-26] mounted on a distal portion and drive means [4/3-5, 8/27-91], the drive means connected in a force-transmitting relationship with the shaft [5/1-2, 24/27, 25/1-2] for transmitting force to move the tip [9/1-3] and wherein the tip separates the portions of fetal tissue [3/20] from the other portions of the donor [4/11-13] (Figs. 1-16).

Claim 58. (Cancelled)

Claim 59. (Previously Presented) The method of claim 57 wherein the shaft further includes a flexible inner member [10/2-3, 8-9] which is rotatable about a central axis of the shaft and an outer member which extends along and encloses the inner member [14/26-27] (Figs. 4-13).

Claim 60. (Previously Presented) The method of claim 59 wherein the outer member has greater rigidity than the inner member [15/5-9].

Claim 61. (Previously Presented) The method of claim 60 wherein the passage is located between the inner and outer members [14/15-16, 15/22-24].

Claims 62-65. (Cancelled)

Claim 66. (Currently Amended) The method of claim 57 wherein the tip includes at least one aspiration opening located on an outer periphery and spaced from a distal end, the at least one aspiration opening operable for fluid communication with the passage [17/12-18/7](Figs. 14A-14G).

Claim 67. (Previously Presented) The method of claim 36 wherein the separated portions of fetal tissue [3/20] are harvested and transplanted into the donor from whom the tissue was removed [7/7-10, 8/4-5].

Claim 68. (Withdrawn) The method of claim 84, said method further comprising the steps of passing at least a portion of the removal apparatus through a cortical bone layer [7/18-19] to a location inside the bone, wherein the separated body tissue is removed from within the bone, contains viable cells [22/14-17; 22/22-25], and is substantially free of cortical bone [4/17-20].

Claim 69. (Withdrawn) The method of claim 68 wherein the removal apparatus includes a flexible shaft with a leading end and the step of removing body tissue includes controlling position of the leading end of the shaft [6/5-7; 20/15-19].

Claim 70. (Withdrawn) The method of claim 68 wherein prior to implantation the at least one component of the separated body tissue is combined with a material selected from the group consisting of tissue grafts, collagen, antibiotics, and a bone growth promoting substance [22/3-5].

Claim 71. (Withdrawn) The method of claim 70 wherein the bone growth promoting substance is hydroxyapatite or tricalcium phosphate [22/5-6].

Claim 72. (Withdrawn) The method of claim 68 wherein an adhesive element is added to the at least one component of the removed body tissue [8/15-17, 21/20-21, 22/8-9].

Claim 73. (Withdrawn) The method of claim 72 wherein the adhesive element is blood or fibrin [22/7-8].

Claim 74. (Withdrawn) The method of claim 68 further comprising the step of adding the at least one component of the separated body tissue to a polymer [23/8-9].

Claim 75. (Withdrawn) The method of claim 68 wherein at least one of the steps of moving and implanting is performed through the cannula [8/6-9].

Claim 76. (Withdrawn) The method of claim 68 wherein at least one of the steps of moving and implanting is performed under endoscopic, arthroscopic, or fiber optic guidance [4/9-10].

Claim 77. (Withdrawn) The method of claim 68 wherein the donor is the patient [7/7-10, 8/3-4, 5-6].

Claim 78. (Withdrawn) The method of claim 68 wherein the at least one component of the separated body tissue is separated from the removed tissue by using a filter [20/26-27, 21/1-2].

Claim 79. (Withdrawn) The method of claim 78 wherein the at least one component of the separated body tissue is implanted with a retainer [23/14-15] (**Fig 18, 19, 19A**).

Claim 80. (Previously Presented) The method of claim 36 further including introducing a sleeve [5/12-13, 15-17] having a plurality of inflatable elements spaced serially [19/2-3], the inflatable elements operable for control of rigidity of the removal apparatus [19/3-4].

Claim 81. (Previously Presented) The method of claim 80 including forming the removal apparatus into a desired shape or position by selectively and individually inflating or deflating the plurality of inflatable elements [19/15-19].

Claim 82. (Previously Presented) The method of claim 36 wherein at least a portion of the removal apparatus is flexible [3/26-27].

Claim 83. (Previously Presented) The method of claim 36 wherein at least a portion of the removal apparatus is movable along a nonlinear path [5/5-7].

Claim 84. (Previously Presented) A method of using body tissue, said method comprising inserting a removal apparatus (**Figs. 1-16**) into a donor percutaneously through a cannula [8/6-14; 22/27-23/5; 23/25-24/14] (**Figs. 18, 19A, and 19B**), guiding the removal apparatus to a desired location within the donor's body [6/5-18; 24/23-27], separating portions of body tissue from other portions of the donor [7/3-6; 9/8-10; 20/26-21/12], moving the separated portions of body tissue along a passage in the removal apparatus by suction [24/10-18; 25/2-4], maintaining viability of the removed separated portions of body tissue for harvesting and transplantation [6/21-22; 7/15-17], and implanting the separated portions of body tissue in a patient [25/8-10].

Claim 85. (Previously Presented) The method of claim 84 wherein the body tissue includes fetal tissue [3/20].

Claim 86. (Previously Presented) The method of claim 84 wherein the body tissue includes bone [3/17].

Claim 87. (Previously Presented) The method of claim 86 wherein the bone includes cancellous bone [4/20].

Claim 88. (Previously Presented) The method of claim 84 further comprising a step of irrigating the body tissue [6/24-25].

Claim 89. (Previously Presented) The method of claim 84 wherein the passage includes a filter [7/3-5].

Claim 90. (Previously Presented) The method of claim 84, further including adding a biodegradable material to the separated portions of body tissue prior to implantation [8/17-18, 23/8].

Claim 91. (Previously Presented) The method of claim 84 wherein the separated portions of fetal tissue [3/20] are harvested and transplanted into the donor from whom the tissue was removed [7/7-10, 8/4-5].

Claim 92. (Previously Presented) The method of claim 57 wherein the tip includes at least one aspiration opening located on a side of the tip, the at least one aspiration opening operable for fluid communication with the passage [17/12-18/7](Figs. 14A-14G).

Claim 93. (Previously Presented) The method of claim 84 wherein the removal apparatus includes a shaft with a tip mounted on a distal portion, the tip operable to separate portions of body tissue from other portions of the donor [24/12-14].

Claim 94. (Previously Presented) The method of claim 96 wherein the tip includes at least one aspiration opening located on a side of the tip, the at least one aspiration opening operable for fluid communication with the passage [17/12-18/7](Figs. 14A-14G),

Claim 95. (Previously Presented) The method of claim 84 wherein at least a portion of the removal apparatus is flexible [3/26-27].

Claim 96. (Previously Presented) The method of claim 84 wherein at least a portion of the removal apparatus is movable along a nonlinear path [5/5-7].

Claim 97. (Previously Presented) The method of claim 36 further comprising the step of expanding at least a portion of at least one of the removal apparatus and cannula [111/3-7; 9/11-12] (Figs. 15 and 16).

Claim 98. (Previously Presented) The method of claim 84 further comprising the step of expanding at least a portion of at least one of the removal apparatus and cannula [111/3-7; 9/11-12] (Figs. 15 and 16).

Claim 99. (Previously Presented) The method of claim 57 wherein the separating step includes cutting body tissue with the tip [4/3-5].

Claim 100. (Previously Presented) The method of claim 93 wherein the separating step includes cutting body tissue with the tip [4/3-5].

Claim 101. (Previously Presented) The method of claim 36 further comprising the step of positioning a trocar with respect to the cannula [23/25-24/1](Figs. 19A and 19B).

Claim 102. (Previously Presented) The method of claim 84 further comprising the step of positioning a trocar with respect to the cannula [23/25-24/1](Figs. 19A and 19B).

Claim 103. (Previously Presented) The method of claim 101 wherein the trocar is positioned within the cannula [23/25-24/1](Figs. 19A and 19B).

Claim 104. (Previously Presented) The method of claim 102 wherein the trocar is positioned within the cannula [23/25-24/1](Figs. 19A and 19B).

Claim 105. (Previously Presented) The method of claim 36 further comprising the step of positioning the cannula with a trocar [23/25-24/1](Figs. 19A and 19B).

Claim 106. (Previously Presented) The method of claim 84 further comprising the step of positioning the cannula with a trocar [23/25-24/1](Figs. 19A and 19B).

Claim 107. (Previously Presented) The method of claim 101 wherein body tissue passes through the trocar [23/13-15; 23/24-24/2](Figs. 19A and 19B).

Claim 108. (Previously Presented) The method of claim 102 wherein body tissue passes through the trocar [23/13-15; 23/24-24/2](Figs. 19A and 19B).

Claim 109. (Previously Presented) The method of claim 36 wherein the donor is the patient [7/7-10, 8/3-4, 5-6].

Claim 110. (Previously Presented) The method of claim 36 further comprising the step of passing at least a portion of an instrument into the cannula [8/6-14; 23/1-5](Fig. 19B).

Claim 111. (Previously Presented) The method of claim 84 further comprising the step of passing at least a portion of an instrument into the cannula [8/6-14; 23/1-5](Fig. 19B).

VI. GROUNDS OF REJECTIONS TO BE REVIEWED ON APPEAL

Rejections under 35 U.S.C. §112

Whether claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 80-111 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph, with respect to “maintaining viability of the removed separated portions”.

Whether claims 101-108 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph. Specifically, claim 101 and 102 with respect to “positioning a trocar with respect to the cannula”, claim 103 and 104 with respect to “the trocar is positioned within the cannula”, claim 105 and 106 with respect to “positioning the cannula with a trocar”, and claim 107 and 108 with respect to “body tissue passes through the trocar”.

Whether claims 110 and 111 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph, with respect to “passing at least a portion of an instrument into the cannula”.

Whether claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 fail to comply with the written description requirement under 35 U.S.C. §112, 2nd paragraph, with respect to “maintaining viability of the removed separated portions” being allegedly unclear about how viability of the tissue is maintained.

Whether claims 110 and 111 fail to comply with the written description requirement under 35 U.S.C. §112, 2nd paragraph, with respect to “passing at least a portion of an instrument into the cannula” and it allegedly being unclear what the instrument is.

Rejection under 35 U.S.C. §103

Whether claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99, and 109 are unpatentable under 35 U.S.C. §103(a) over Rudall K.M., Wickham, G.A. “Development of wool follicles and fibers on autoplasic grafts of stored foetal lamb skin,” pp. 75-88 of book titled “Biology of the skin and hair growth,” American Elsevier Publishing Company, Inc., 1965, in view of Kellogg (US 3,606,878).

ARGUMENTS

A. Rejections under 35 U.S.C. §112, first paragraph

1. Applicable Law- 35 U.S.C. §112, first paragraph

The first paragraph of 35 U.S.C. 112 is directed to enablement:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same, and shall set forth the best mode contemplated by the inventor of carrying out his invention.

There are two separate requirements set forth in this paragraph: (1) the claims must be supported by an enabling disclosure within the specification; and (2) the specification must disclose the best mode for carrying out the invention. The following §112 rejections are directed to the first requirement. *See* MPEP §2164.

2. Status of Arguments

The rejection of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 under 35 U.S.C. §112, first paragraph were first presented by the Examiner in a final Office Action mailed April 2, 2010. Additionally, the rejection of claims 101-108 and 110-111 under 35 U.S.C. §112, first paragraph were in part first presented and in part previously presented by the Examiner in the final Office Action mailed April 2, 2010. The arguments presented herein regarding the rejection under 35 U.S.C. §112, first paragraph, have been previously presented in part, and are new in part.

3. Argument

- i. **Whether claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 80-111 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph, with respect to “maintaining viability of the removed separated portions”.**

Claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 are supported by enabling disclosure with respect to “maintaining the viability of the removed separated portions”. For example, page 6, line 19-22 of the specification as originally filed states “[f]luid may be injected through the flexible drill shaft to a location adjacent the cutting tip to increase the efficiency of the tissue removal and to ***limit thermal necrosis***”, page 7, lines 10-14 states “[i]n order to ***maintain the sterility*** of the tissue removed, the entire suction apparatus including the suction passage and the trap or filter is sterilized, and if necessary, is disposable”, and page 7, line 15-17 states “work is done by going percutaneously through the skin to a specific tissue area to ***minimize the damage*** to skin, muscle, and bone”. (Emphasis Added). *In ipsius verbis* (in the same words) disclosure is not necessary to satisfy the written description requirement of section 112. Instead, the disclosure need only reasonably convey to persons skilled in the art that the inventor had possession of the subject matter in question. *Fujikawa v. Wattanasin*, 93 F.3d 1559 (Fed. Cir. 1996).

- ii. **Whether claims 101-108 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph. Specifically, claim 101 and 102 with respect to “positioning a trocar with respect to the cannula”, claim 103 and 104 with respect to “the trocar is positioned within the cannula”, claim 105 and 106 with respect to “positioning the cannula with a trocar”, and claim 107 and 108 with respect to “body tissue passes through the trocar”.**

Claims 101-108 and 110-111 are supported by enabling disclosure with respect to positioning a trocar with respect to the cannula; (2) positioning the cannula with a trocar; and (3) positioning a trocar within the cannula. Support for a cannula may be found, for example, with reference to outer sleeve 44 in Figs. 5-7; outer sleeve 56 in Fig. 8, outer sleeve 60 in Figs. 9-11; outer sleeve 88 in Fig. 12; and outer sleeve 112 in Fig. 13, and associated text in the specification, showing and describing cannulas. Cannulas of the invention are also discussed, generally, on page 8 lines 6-11, including using a drill or curette through the cannula; page 23 lines 1-5; and page 23 line 26-27.

A trocar, as defined for example in Dictionary.com, is “A sharp-pointed surgical instrument, used with a cannula to puncture a body cavity for fluid aspiration”. The

aforementioned examples, all are used with the cutting tool shown for example in Fig. 3 and 14A-14G, and are disclosed in the specification for aspiration (e.g. Figs. 5-11), including aspiration of body tissue (e.g. page 5 line 4 *et seq.*), and therefore meet the definition of trocar. As cited in the immediately preceding section, it is not necessary for the claims to be supported by their exact words in the specification.

iii. **Whether claims 110 and 111 fail to comply with the written description requirement under 35 U.S.C. §112, 1st paragraph, with respect to “passing at least a portion of an instrument into the cannula”.**

Claims 110 and 111 are supported by enabling disclosure with respect to “passing at least a portion of an instrument into the cannula”. For example, page 19, line 1-3 of the specification as originally filed states “[d]isposed within the sleeve 150 is a guidance mechanism 152” and figures 15 and 16 illustrate passing at least a portion of an instrument into the cannula. As another example, page 23, lines 3-4 of specification as originally filed states “[a] curette or probe is then inserted through the cannula 182”, page 24, lines 1-2 of the specification as originally filed states “[it] is then packed in place as desired using a suitable instrument”. Figures 15-16 and 19A-19B, and associated text, further illustrate passing at least a portion of an instrument into the cannula.

As claims 101-108 comply with the written description requirement, the rejections under 35 U.S.C. §112, 1st paragraph should be withdrawn.

4. Conclusion of §112 1st Paragraph Arguments

In accordance with the foregoing, the claims particularly point out and distinctly claim the subject matter which the Appellant regards as his invention. Therefore, the Appellant respectfully suggests that the rejection of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 under 35 U.S.C. §112, first paragraph has been overcome and should be withdrawn.

B. Rejections under 35 U.S.C. §112, second paragraph

1. Applicable Law- 35 U.S.C. §112, second paragraph

The second paragraph of 35 U.S.C. 112 is directed to indefiniteness:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

The essential inquiry pertaining to this requirement is whether the claims set out and circumscribe a particular subject matter with a reasonable degree of clarity and particularity. Definiteness of claim language must be analyzed, not in a vacuum, but in light of: (A) the content of the particular application disclosure; (B) the teachings of the prior art; and (C) the claim interpretation that would be given by one possessing the ordinary level of skill in the pertinent art at the time the invention was made. *See* MPEP §2173.02. Accordingly, even if a claim term that is not used or defined in the specification, it is not indefinite if the meaning of the claim term is discernible. *See* MPEP §2173.02 (citing *Bancorp Services, L.L.C. v. Hartford Life Ins. Co.*, 359 F.3d 1367, 1372, 69 USPQ2d 1996, 1999-2000 (Fed. Cir. 2004)).

However, if the language used by applicant satisfies the statutory requirements of 35 U.S.C. 112, second paragraph, but the examiner merely wants the applicant to improve the clarity or precision of the language used, the claim must not be rejected under 35 U.S.C. 112, second paragraph, rather, the examiner should suggest improved language to the applicant. *See* MPEP §2173.02.

2. Status of Arguments

The rejection of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 under 35 U.S.C. §112, second paragraph were first presented by the Examiner in a final Office Action mailed April 2, 2010. Additionally, the rejection of claims 110-111 under 35 U.S.C. §112, second paragraph were presented by the Examiner in the final Office Action mailed April 2, 2010. The arguments presented herein regarding the rejection under 35 U.S.C. §112, second paragraph, are new in part, and have not been previously considered by the Examiner.

3. Argument

- i. **Whether claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 fail to comply with the written description requirement under 35 U.S.C.**

§112, 2nd paragraph, with respect to “maintaining viability of the removed separated portions” being allegedly unclear about how viability of the tissue is maintained.

Claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 comply with the written description requirement under 35 U.S.C. §112, second paragraph, with respect to “maintaining viability of the removed separated portions”. The applicable standard, as stated in *Metabolite Labs., Inc. v. Lab. Corp. of Am. Holdings*, 370 F.3d 1354, 1366, 71 USPQ2d 1081, 1089 (Fed. Cir. 2004), is "The requirement to 'distinctly' claim means that the claim must have a meaning discernible to one of ordinary skill in the art when construed according to correct principles..Only when a claim remains insolubly ambiguous without a discernible meaning after all reasonable attempts at construction must a court declare it indefinite."

Claim 1 recites “maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation”; claim 84 is similar, reciting instead ‘body’ tissue. One of ordinary skill in the art would understand and be able to discern viability in the context of retrieving cells for the purposes of harvesting, or for transplantation.

ii. **Whether claims 110 and 111 fail to comply with the written description requirement under 35 U.S.C. §112, 2nd paragraph, with respect to “passing at least a portion of an instrument into the cannula” and it allegedly being unclear what the instrument is.**

Claims 110 and 111 recite “*an* instrument” (emphasis added). The specification contains numerous examples of instruments, including, for example, the flexible drills of Figs. 3 or 15-16, or the sleeve of Fig. 19A-19B. Because a specific antecedent for an instrument is not required, any suitable instrument in light of the combined claims and the specification would meet the claim, and therefore claims 110 and 111 are sufficiently clear.

4. Conclusion of §112 2nd Paragraph Arguments

In accordance with the foregoing, the claims particularly point out and distinctly claim the subject matter which the Appellant regards as his invention. Therefore, the Appellant respectfully suggests that the rejection of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, and 80-111 under 35 U.S.C. §112, second paragraph has been overcome and should be withdrawn.

C. Rejections under 35 U.S.C. §103(a)

1. Applicable Law - 35 U.S.C. § 103(a)

35 U.S.C. § 103(a) imposes the requirement that a claimed invention, to be patentable, must be non-obvious over the prior art “at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.”

The starting point for discussions of obviousness is *Graham v. John Deere Co.*, 383 U.S. 1 148 USPQ 459 (1966), which set forth the following factors for determining obviousness: (1) the scope and content of the prior art; (2) differences between the prior art and the claims at issue; (3) the level of ordinary skill in the pertinent art; and (4) secondary considerations such as commercial success, long felt but unresolved needs, and failure of others.

All evidence, including the secondary considerations, must be weighed before reaching a conclusion on obviousness under § 103. *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1561, 1 USPQ2d 1593, 1594 (Fed. Cir.), cert. denied, 481 U.S. 1052 (1986); *Hodosh v. Block Drug*, 786 F.2d 1136, 1143, 229 USPQ 182, 188 (Fed. Cir.), cert. denied, 479 U.S. 827 (1986). In addition, the prior art itself must suggest the desirability and, therefore, obviousness of a modification of a reference or the combination of references to achieve a claimed invention without looking to the patent or application under consideration. *Hodosh*, 786 F.2d at 1143 n.5, 229 USPQ at 187 n.5; *In re Gordon*, 733 F.2d 900, 902, 221 USPQ 1125, 1127 (Fed. Cir. 1984).

Knowledge is presumed of all references in the same field of invention as the applicant’s. However, the test of whether it would have been obvious to select specific teachings and combine them as the applicant did must still be met by identification of some suggestion, teaching, or motivation (TSM test) in the prior art, arising from what the prior art would have taught one of ordinary skill in the art. *In re Fine*, 837 F.2d 1071, 1075, 5 USPQ2d 1596, 1600 (Fed. Cir. 1988).

Although the Supreme Court recently rejected a rigid application of the “teaching, suggestion, motivation (TSM) test”, the Court also recognized that a showing of “teaching, suggestion, motivation” to combine the prior art to meet the claimed subject matter could provide a helpful insight in determining whether the claimed subject matter is obvious. *KSR Int’l Co. v. Teleflex Inc.* 550 U.S. 398; 82 USPQ2d 1385 (2007). Therefore, it remains

necessary to identify the reason(s) why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed in order to properly establish a *prima facie* case of obviousness.

2. Status of Arguments

The arguments presented in this Appeal Brief regarding 35 U.S.C. §103(a) are substantially new, but may include restatements of certain aspects of arguments presented earlier. Arguments of the Examiner with respect to Rudall and Kellogg were presented in earlier Office Actions.

3. Argument

Claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99 and 109 are patentable under 35 U.S.C. §103(a) over Rudall et al. (Biology of the Skin and Hair Growth, American Elsevier Publishing Company, Inc., Chapter 5, Pages 75-88, 1965; hereinafter “Rudall”) in view of Kellogg (U.S. Patent No. 3,606,878; hereinafter “Kellogg”). For the reasons set forth below, Applicant respectfully submits that this rejection should be withdrawn.

- i. **Whether claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99, and 109 are unpatentable under 35 U.S.C. §103(a) over Rudall K.M., Wickham, G.A. “Development of wool follicles and fibers on autoplasic grafts of stored foetal lamb skin,” pp. 75-88 of book titled “Biology of the skin and hair growth,” American Elsevier Publishing Company, Inc., 1965, in view of Kellogg (US 3,606,878).**

Independent claim 36 currently recites “a method of using fetal body tissue, said method comprising inserting a removal apparatus into a donor percutaneously through a cannula, guiding the removal apparatus to a desired location within the donor’s body, separating portions of fetal tissue from other portions of the donor, moving the separated portions of fetal tissue along a passage in the removal apparatus by suction, maintaining viability of the removed separated portions of fetal tissue for harvesting and transplantation, and implanting the separated portions of fetal tissue in a patient”.

As established in a previous response by the Applicant, Rudall describes removing skin from a gravid uterus that has been exteriorized through a six inch incision. (e.g. Page 76, Paragraph 6 of Rudall). Rudall requires an incision of this size in order to externalize the uterus together with the fetus, the uterus being wrapped in towels soaked in saline while the skin is

being removed. *See* Page 76, Paragraph 6 – Page 77, Paragraph 1. After the skin is removed the excised uterus, the uterus is replaced back into the mother. (Page 77, Paragraph 1 of Rudall). Nowhere does Rudall teach, *inter alia*, 1) inserting a removal apparatus into a donor, 2) percutaneously through a cannula, 3) guiding the removal apparatus to a desired location within the donor's body, or 4) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction.

As also discussed in previous Response(s), Kellogg teaches a biopsy device with an elongated tubular stylet or hollow needle body 10 with a bluntly-pointed tip 12 for nonincisional penetration of intervening tissues. *See* Col 1, Ln 29-30 and Col 2., Ln. 2, and Col. 2, Ln. 40-44. As an initial matter, Kellogg discusses body 10 as part of the biopsy device with a bluntly-pointed tip, but does not teach removal apparatus and a cannula for insertion of the removal apparatus. Second, because Kellogg discloses a bluntly-pointed tip obstructing the passage, body 10 would not allow insertion of a removal apparatus through its passage. *See* Fig. 5. Third, Kellogg merely teaches that suction “helps retain the specimen in the cutter cup” (Col. 1, Ln. 19), “[s]uction applied to the needle passage behind the cutter is communicated through the cutter to the needle passage forward of the cutter” (Col. 2, Ln. 14), and “suction helps hold the specimen reliably within the cup or cavity of the cutter for subsequent removal after the needle is withdrawn from the patient” (Col. 2, Ln. 19), but does not disclose moving tissue along a passage in the removal apparatus by suction. As such, Kellogg merely discloses a removal apparatus not a cannula and suction applied forward of the cutter not through a passage in the cutter. Nowhere does Kellogg teach, *inter alia*, 1) inserting a removal apparatus into a donor percutaneously through a cannula, 2) separating portions of fetal tissue from other portions of the donor, or 3) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction.

Furthermore, one of skill in the art would not combine Rudall and Kellogg. Rudall teaches the creating a six inch incision to exteriorize a uterus and removing skin from the uterous while it is outside the fetus. In contrast, Kellogg teaches a biopsy device for nonincisional penetration and extracting of tissues. One of skill in the art would not combine a nonincisional device with a procedure that requires an incision, as a nonincisional device would not allow for exteriorization of a uterus. Also, one of skill in the art would not combine Rudall's procedure

requiring removal of skin on the surface of a uterus with Kellogg's biopsy device for penetration of intervening tissues to reach internal organs, membranes and tissues, because removal of skin from an exteriorized uterus does not require penetration of intervening tissues. As such, one of skill in the art would not combine Rudall and Kellogg.

Moreover, even if Rudall and Kellogg were combined, the proposed combination does not teach or suggest 1) inserting a removal apparatus into a donor percutaneously through a cannula and 2) moving the separated portions of fetal tissue along a passage in the removal apparatus by suction. Thus, even if one of ordinary skill in the art attempted to combine these references, one would still be lacking elements and thus would not obtain the method as currently claimed. Therefore, the combination of Rudall and Kellogg is not sufficient to establish a proper case of *prima facie* obviousness, as the combination does not teach or suggest all of the limitations of the method as currently claimed.

Independent claim 84 recites "a method of using body tissue, said method comprising inserting a removal apparatus into a donor percutaneously through a cannula, guiding the removal apparatus to a desired location within the donor's body, separating portions of body tissue from other portions of the donor, moving the separated portions of body tissue along a passage in the removal apparatus by suction, maintaining viability of the removed separated portions of body tissue for harvesting and transplantation, and implanting the separated portions of body tissue in a patient."

In the interest of brevity, the above discussion of Rudall and Kellogg is incorporated herein by reference.

As noted in the foregoing section, the proposed combination of Rudall and Kellogg does not teach or suggest 1) inserting a removal apparatus into a donor percutaneously through a cannula and 2) moving the separated portions of body tissue along a passage in the removal apparatus by suction. Thus, even if one of ordinary skill in the art attempted to combine these references, one would still be lacking elements and thus would not obtain the method as currently claimed. Therefore, the combination of Rudall and Kellogg is not sufficient to establish a proper case of *prima facie* obviousness, as the combination does not teach or suggest all of the elements of the method as currently claimed.

Therefore, in view of the remarks and arguments given above, independent claims 36 and 84 and their dependent claims, distinguish over Rudall and Kellogg, alone or in combination with each other, at least for the reasons detailed. In view of the foregoing remarks and arguments, the rejection of claims 36, 38-40, 46-50, 53, 57, 59-61, 66-67, 84-85, 88, 90-96, 99, and 109 should be reversed.

4. Conclusion of §103 Arguments

According to the foregoing, claims 36 and 84 are patentable over a combination of Rudall and Kellogg. Because claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 92, 99, and 109 depend from claim 36 and claims 85, 88, 90-91, and 93-95 depend from claim 84, these dependent claims necessarily include all the elements of their base claim. Accordingly, Applicant respectfully submits that the dependent claims are allowable over the cited references at least for the same reasons.

In light of the foregoing, Applicant respectfully submits the foregoing rejections under §103 should be reversed.

PRAYER FOR RELIEF

Applicant respectfully prays that the Board reverses the Examiner's rejections of claims 36, 38-43, 46-50, 53, 57, 59-61, 66-67, 84-85, and 88-111. Applicant further requests an opportunity to rejoin withdrawn claims as appropriate. In addition, in light of the reversal, the Board is requested to order a Notice of Allowance be issued.

A fee of \$1,175 for a five months extension is believed to be due, and is submitted herewith. However, please charge any required fee (or credit any overpayments of fees) to the Deposit Account of the undersigned, Account No. 500601 (Docket No. 780-A02-14-7).

Respectfully submitted,

/ Paul D. Bianco /

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VIII. CLAIMS APPENDIX

The following claim listing reflects the claims as submitted in Applicant's response sent/received on December 10, 2009.

Claims 1-35. (Cancelled)

Claim 36. (Currently Amended) A method of using fetal body tissue, said method comprising inserting a removal apparatus into a donor percutaneously through a cannula ~~percutaneous incision, wherein the removal apparatus includes a shaft that is at least partially flexible,~~ guiding the removal apparatus to a desired location within the donor's body, ~~the removal apparatus movable along a non-linear path,~~ separating portions of fetal tissue from other portions of the donor, moving the separated portions of fetal tissue along a passage in the removal apparatus by suction, maintaining ~~sterility~~ viability of the removed separated portions of fetal tissue for harvesting and transplantation, and implanting the separated portions of fetal tissue in a patient.

Claim 37. (Cancelled)

Claim 38. (Previously Presented) The method of claim 57 wherein a rotating motion is used to separate the portions of fetal tissue.

Claim 39. (Previously Presented) The method of claim 57 wherein a reciprocating motion is used to separate the portions of fetal tissue.

Claim 40. (Previously Presented) The method of claim 36 further comprising a step of irrigating the fetal tissue.

Claim 41. (Previously Presented) The method of claim 40 wherein irrigating and applying suction alternates.

Claim 42. (Previously Presented) The method of claim 40 wherein irrigating and applying suction occur substantially simultaneously.

Claim 43. (Previously Presented) The method of claim 36 wherein the passage includes a filter.

Claims 44-45. (Cancelled)

Claim 46. (Previously Presented) The method of claim 36 further including, prior to implantation, combining the separated portions of fetal tissue with a material selected from the group consisting of tissue grafts, collagen, and bone growth promoting substances.

Claim 47. (Previously Presented) The method of claim 36 further including adding an adhesive element to the separated portions of fetal tissue prior to implantation.

Claim 48. (Previously Presented) The method of claim 47 wherein the adhesive element is blood or fibrin.

Claim 49. (Previously Presented) The method of claim 36, further including adding a biodegradable material to the separated portions of fetal tissue prior to implantation.

Claim 50. (Previously Presented) The method of claim 36 further including adding a polymer to the separated portions of fetal tissue prior to implantation.

Claims 51-52. (Cancelled)

Claim 53. (Currently Amended) The method of claim 36 wherein separating is performed through the cannula.

Claims 54-56. (Cancelled)

Claim 57. (Currently Amended) The method of claim 36 wherein the removal apparatus includes [[the]] a shaft includes with a ~~cutting~~ tip mounted on a distal portion and drive means, the drive means connected in a force-transmitting relationship with the shaft for transmitting force to move the ~~cutting~~ tip and wherein ~~cutting with~~ the ~~cutting~~ tip separates the portions of fetal tissue from the other portions of the donor.

Claim 58. (Cancelled)

Claim 59. (Previously Presented) The method of claim 57 wherein the shaft further includes a flexible inner member which is rotatable about a central axis of the shaft and an outer member which extends along and encloses the inner member.

Claim 60. (Previously Presented) The method of claim 59 wherein the outer member has greater rigidity than the inner member.

Claim 61. (Previously Presented) The method of claim 60 wherein the passage is located between the inner and outer members.

Claims 62-65. (Cancelled)

Claim 66. (Currently Amended) The method of claim 57 wherein the ~~cutting~~ tip includes at least one aspiration opening[[s]] located on an outer periphery and spaced from a distal end, the at least one aspiration opening[[s]] operable for fluid communication with the passage.

Claim 67. (Previously Presented) The method of claim 36 wherein the separated portions of fetal tissue are harvested and transplanted into the donor from whom the tissue was removed.

Claim 68. (Currently Amended) ~~[[A]] The method of using body tissue claim 84, said method further comprising the steps of moving at least a portion of a shaft of an elongate member through a percutaneous incision in a donor such that a leading end of the shaft is located within cortical confines of~~ passing at least a portion of the removal apparatus through a cortical bone layer to a location inside the bone; removing body tissue from the donor through the percutaneous incision, whereby the removed , wherein the separated body tissue is removed from within the bone, contains viable cells, and is substantially free of hard cortical bone; conveying the removed body tissue along a passage in the shaft under the influence of suction; and implanting at least one component of the removed body tissue in a patient, wherein the at least one component includes viable cells and is maintained sterile until implantation.

Claim 69. (Currently Amended) The method of claim 68 wherein the removal apparatus includes a flexible shaft with a leading end and the step of removing body tissue includes controlling position of the leading end of the shaft, ~~the shaft flexible such that the leading end is movable along a nonlinear path.~~

Claim 70. (Currently Amended) The method of claim 68 wherein prior to implantation the at least one component of the ~~removed~~ separated body tissue is combined with a material selected from the group consisting of tissue grafts, collagen, antibiotics, and a bone growth promoting substance.

Claim 71. (Previously Presented) The method of claim 70 wherein the bone growth promoting substance is hydroxyapatite or tricalcium phosphate.

Claim 72. (Previously Presented) The method of claim 68 wherein an adhesive element is added to the at least one component of the removed body tissue.

Claim 73. (Previously Presented) The method of claim 72 wherein the adhesive element is blood or fibrin.

Claim 74. (Currently Amended) The method of claim 68 further comprising the step of adding the at least one component of the ~~removed~~ separated body tissue to a polymer.

Claim 75. (Currently Amended) The method of claim 68 wherein at least one of the steps of ~~removing~~ moving and implanting is performed through ~~[[a]]~~ the cannula.

Claim 76. (Currently Amended) The method of claim 68 wherein at least one of the steps of ~~removing~~ moving and implanting is performed under endoscopic, arthroscopic, or fiber optic guidance.

Claim 77. (Previously Presented) The method of claim 68 wherein the donor is the patient.

Claim 78. (Currently Amended) The method of claim 68 wherein the at least one component of the ~~removed~~ separated body tissue is separated from the removed tissue by using a filter.

Claim 79. (Currently Amended) The method of claim 78 wherein the at least one component of the ~~removed~~ separated body tissue is implanted with a retainer.

Claim 80. (Previously Presented) The method of claim 36 further including introducing a sleeve having a plurality of inflatable elements spaced serially, the inflatable elements operable for control of rigidity of the removal apparatus.

Claim 81. (Previously Presented) The method of claim 80 including forming the removal apparatus into a desired shape or position by selectively and individually inflating or deflating the plurality of inflatable elements.

Claim 82. (New) The method of claim 36 wherein at least a portion of the removal apparatus is flexible.

Claim 83. (New) The method of claim 36 wherein at least a portion of the removal apparatus is movable along a nonlinear path.

Claim 84. (New) A method of using body tissue, said method comprising inserting a removal apparatus into a donor percutaneously through a cannula, guiding the removal apparatus to a desired location within the donor's body, separating portions of body tissue from other portions of the donor, moving the separated portions of body tissue along a passage in the removal apparatus by suction, maintaining viability of the removed separated portions of body tissue for harvesting and transplantation, and implanting the separated portions of body tissue in a patient.

Claim 85. (New) The method of claim 84 wherein the body tissue includes fetal tissue.

Claim 86. (New) The method of claim 84 wherein the body tissue includes bone.

Claim 87. (New) The method of claim 86 wherein the bone includes cancellous bone.

Claim 88. (New) The method of claim 84 further comprising a step of irrigating the body tissue.

Claim 89. (New) The method of claim 84 wherein the passage includes a filter.

Claim 90. (New) The method of claim 84, further including adding a biodegradable material to the separated portions of body tissue prior to implantation.

Claim 91. (New) The method of claim 84 wherein the separated portions of fetal tissue are harvested and transplanted into the donor from whom the tissue was removed.

Claim 92. (New) The method of claim 57 wherein the tip includes at least one aspiration opening located on a side of the tip, the at least one aspiration opening operable for fluid communication with the passage.

Claim 93. (New) The method of claim 84 wherein the removal apparatus includes a shaft with a tip mounted on a distal portion, the tip operable to separate portions of body tissue from other portions of the donor.

Claim 94. (New) The method of claim 96 wherein the tip includes at least one aspiration opening located on a side of the tip, the at least one aspiration opening operable for fluid communication with the passage

Claim 95. (New) The method of claim 84 wherein at least a portion of the removal apparatus is flexible.

Claim 96. (New) The method of claim 84 wherein at least a portion of the removal apparatus is movable along a nonlinear path.

Claim 97. (New) The method of claim 36 further comprising the step of expanding at least a portion of at least one of the removal apparatus and cannula.

Claim 98. (New) The method of claim 84 further comprising the step of expanding at least a portion of at least one of the removal apparatus and cannula.

Claim 99. (New) The method of claim 57 wherein the separating step includes cutting body tissue with the tip.

Claim 100. (New) The method of claim 93 wherein the separating step includes cutting body tissue with the tip.

Claim 101. (New) The method of claim 36 further comprising the step of positioning a trocar with respect to the cannula.

Claim 102. (New) The method of claim 84 further comprising the step of positioning a trocar with respect to the cannula.

Claim 103. (New) The method of claim 101 wherein the trocar is positioned within the cannula.

Claim 104. (New) The method of claim 102 wherein the trocar is positioned within the cannula.

Claim 105. (New) The method of claim 36 further comprising the step of positioning the cannula with a trocar.

Claim 106. (New) The method of claim 84 further comprising the step of positioning the cannula with a trocar.

Claim 107. (New) The method of claim 101 wherein body tissue passes through the trocar.

Claim 108. (New) The method of claim 102 wherein body tissue passes through the trocar.

Claim 109. (New) The method of claim 36 wherein the donor is the patient.

Claim 110. (New) The method of claim 36 further comprising the step of passing at least a portion of an instrument into the cannula.

Claim 111. (New) The method of claim 84 further comprising the step of passing at least a portion of an instrument into the cannula.

IX. EVIDENCE APPENDIX

Dictionary Definition of “TROCAR” from web site:

[dictionary.reference.com/browse/trocar...](http://dictionary.reference.com/browse/trocar)

X. RELATED PROCEEDINGS APPENDIX

None.